REMARKS

The Final Action mailed March 19, 2008, has been carefully reviewed. The claims in the application, upon entry of the present amendment with the filing of the attached RCE, are claims 10, 11, 16-18, 20 and 21. These claims meet all the requirements for patentability including those of Sections 112, 102 and 103, whereby such claims should be allowed. Favorable reconsideration and allowance are therefore earnestly solicited.

The examiner is thanked for noticing the clerical error in claim 20 which now is corrected above.

Claims 10, 20 and 21 have been rejected under the first paragraph under Section 112 as failing to comply with the written description requirement. The rejection is respectfully traversed for the reason of record, respectfully repeated by reference.

Applicants simply cannot understand the examiner's position, because there should be no doubt whatsoever that claims 10, 20 and 21 as previously submitted fully meet the written description requirement. This is demonstrated by the scope of the original claims, the abstract as filed and

several paragraphs of the specification as filed, including paragraphs [0007], [0009], [0010] and [0012].

Nevertheless, to advance prosecution but with no intention to dedicate, disclaim, abandon or otherwise give up any subject matter whatsoever, and reserving of the right to pursue broader and other claims in a continuing application without any penalty whatsoever, applicants have restricted the claims in the present application to nephropathy.

Withdrawal of the rejection is respectfully requested.

Claims 10-21 have been rejected again as anticipated by Shishido. The rejection is respectfully traversed for the reasons of record, respectfully repeated by reference, and for the additional reasons given below.

Shishido indicates that end-stage renal failure patients were treated with G-CSF, and it was found to be an effective therapeutic agent for neutropenia and neutrophils dysfunction in patients with renal failure. Shishido does not, however, disclose, suggest, or teach that G-CSF is effective for proliferating or regenerating renal tissue in a disease state of nephropathy.

As disclosed in the present specification in paragraph [0007], renal failure and nephropathy are different

diseases. Particularly, the treatment of neutropenia and neutrophils dysfunction in patients with renal failure is entirely irrelevant to the proliferation or regeneration of nephropathy of renal tissue. It is clear that the present invention is noval over Shishido.

Withdrawal of the rejection is respectfully requested.

Claim 10 has been again rejected under Section 102 as anticipated by Pierce, and claims 18 and 19 are also so rejected. This rejection is respectfully traversed for the reasons of record, respectfully repeated by reference, and for the additional reasons set forth below.

Pierce discloses a method for promoting accelerated wound healing in an injured patient by topical administration of GM-CSF (claim 1). Pierce states that "the term 'injury' shall be defined as a wound which extends from the surface of a patient's skin into the underlying tissue" (column 11, lines 7-9). Further, Pierce states that "Because the typical wound is localized, cell types needed to effect wound repair must be concentrated in and around the injured area" (column 10, lines 38-40). From these recitations, it is absolutely clear that the type wound of referred to by Pierce is a skin wound. This is also supported by column 1, in the description regarding

"A. Wounds and Wound Healing", that the term "wound" is a skin wound.

Pierce is entirely irrelevant to the proliferation or regeneration of nephropathy of renal tissue. In addition, Pierce use GM-CSF which is clearly different from G-CSF. It is absolutely clear that the present invention is novel over Pierce.

Withdrawal of the rejection is in order and is respectfully requested.

Claim 10-21 have been rejected under Section 102(e) as being anticipated by Fukuda. This is a new rejection, claim 10 (previously pending) not having been previously rejected on the basis of Fukuda, although other claims (deleted in the last reply) were rejected as anticipated by Fukuda. The rejection is respectfully traversed.

First, it is improper and unfair for the PTO to have instituted a Final rejection on the basis of Fukuda which was not previously applied against claim 10. Applicants strongly object. The Amendments made in claim 10 did not justify a new rejection.

Nevertheless, the rejection is respectfully submitted to be entirely unjustified.

Fukuda relates to a method for treating an ischemic disease by administering a combination of G-CSF and hepatocyte growth factor (HGF) (claim 1). Administration of G-CSF and HGF contributes to vasculogenesis in a patient, in the treatment of ischemic diseases ([0058]). Therefore, the treatment of Fukuda is entirely different from the present invention which relates to repairing/regenerating renal tissue in a state of nephropathy by administering G-CSF only.

The claims have been amended to repairing/ regenerating renal tissue of nephropathy. Fukuda does not disclose, suggest or teach the use of G-CSF in repairing/regenerating renal tissue of nephropathy.

On page 6, second paragraph of the Final Action, the examiner asserts that "Fukuda clearly states that G-CSF and HGF can be prepared and administered as single preparation or alternatively, they can be prepared separately, and administered on different occasions ([0057])". However, this recitation clearly means that the administration of both G-CSF and HGF is necessary for the treatment even if they are administered separately, i.e. they must both be administered whether together or separately, and it does not mean that the administration of only G-CSF can be effective.

It is clear that the present invention is not anticipated by Fukuda. Withdrawal of the rejection is respectfully requested.

Applicants respectfully request favorable reconsideration and allowance.

Respectfully submitted,

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